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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,950	11/16/2005	Thomas Herget	DFMP-P01-480	1016

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,950	HERGET ET AL.	
	Examiner	Art Unit	
	TIMOTHY P. THOMAS	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,23,27-35,42,43 and 46-56* is/are pending in the application.

4a) Of the above claim(s) *1-8,12-14,19,20,23,27,29-31,42,43,46-51,54 and 56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11,15-18,28,32-35,52,53 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/31/2005; 1/26/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group VII, claims 9-18, 23, 27-35, 52-56 (all in part) (a method of regulating the production of Hepatitis C Virus and/or preventing and/or treating HCV infection comprising administration of all trans retinoic acid, a derivative thereof or 4-HPR) in the reply filed on 2/14/2008 is acknowledged. The traversal is on the ground(s) that the Examiner has failed to raise a valid rejection under PCT Rule 13.1, with the argument that the technical feature linking Groups V-VIII is not the "agent", but the agents' common ability to regulate HCV production in a host that constitutes the special technical feature. This is not found persuasive because 1) the compounds of the Markush group consist of different chemical compounds with completely different structures; for example, selenium and Vitamin D3 are both recited in claim 1 as members of a group of agents, selenium is an element, whereas vitamin D3 is an unrelated organic compound; therefore, the compounds lack a common core structure and are therefore not linked by a technical feature in common; and 2) considering applicant's argument that the common property of the different agents (i.e., the ability to regulate HCV production) is the technical feature in common among the agents is considered, the point may be made that Bankit (US 4,668,515), which teaches sodium selenite (a selenium salt) at concentrations overlapping with the instant disclosure is a composition that inherently has the properties required by the composition of claim 1 (i.e., "useful for the treatment of a disease associated with a

HCV infection"), as disclosed by applicant. Therefore, for both of these reasons the position is still maintained that unity of invention in the claims is lacking.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's election with traverse of all trans retinoic acid (corresponding to specie (i)), and an in vivo method; with the identification that claims 9-11, 13-18, 23, 27-29, 31-35 and 32-56 read on all trans retinoic acid and claims 9-18, 23, 27-35, and 52-56 in the reply filed on 2/14/2008 is acknowledged. The traversal is on the ground(s) that 1) there is no rationale for the species election requirement; 2) species 1 (using a single active agent) is not even recited in the claims, and has therefore been artificially conjured; and 3) in vivo vs. in vitro specie requirement has not been established as lacking unity, and there is no additional search burden to examine both together. This is not found persuasive because 1) the rationale is the same as that explained above, the compounds lack a common special technical feature, a priori; 2) the administration of a single active agent is an embodiment within claim 9, for example; the phrase "at least one agent" includes 1) administration of any one of the agents recited in claim 9 (specie (i)) and 2) administration of more than one of the agents in claim 9; the language "further comprises at least one of the following compounds" in claim 13 also includes 3) the administration of one compound from claim 9 and one compound from claim 13 or 14 (specie (ii)), 4) the administration of one compound from claim 9 with more than one compound from claim 13 or 14; or 5) combinations of more than one compound from each of claim 9 and 13 or 14 (2), 4) and 5) would be encompassed within specie (iii)). Since the compounds, (considering specie (i)) do not comprise a proper Markush group

as outlined above (e.g., selenium and Vitamin D3 do not have common structural features, and therefore do not comprise a proper Markush group); and, as additionally outlined above, sodium selenite, taught by Bankit inherently has the same properties as required by claim 1, the position is maintained that the species lack a special technical feature, and therefore lack unity. 3) The feeding of sodium selenite to a mammal, as pointed out in the Bankit teaching, is a teaching of one of the two in vivo and in vitro species; therefore the species lacks a special technical feature linking the two species; search burden is not relevant to Lack of Unity determinations.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 1-8, 19-20, 42-43 and 46-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/14/2008.

4. Claims 12-14, 23, 27, 29-31, 54 and 56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/14/2008.

Specification

5. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) The Names Of The Parties To A Joint Research Agreement: See 37 CFR 1.71(g).

(e) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

(f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward

the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(l) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

6. The disclosure is objected to because of the following informalities: There is no section "Brief Description of the Drawings", Item (h) above.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 17 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claims 17 and 34, the terms "preferably", "more preferably" and "particularly" render the claims indefinite because it is unclear whether the limitation(s) following the terms are part of and further limit the claimed invention.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 9-11, 15-18, 28, 32-35, 52-53, 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating Hepatitus C, does not reasonably provide enablement for preventing Hepatitis C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make or use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method for regulating the production of Hepatitis C virus in an individual and/or for preventing and/or treating hepatitis C virus infection and/or diseases associated with HCV infection in an individual, comprising administering a pharmaceutical composition comprising at least one agent, including the elected compound all-trans-retinoic acid to the individual. Thus, the claims taken together with the specification imply administration of all-trans-retinoic acid will prevent hepatitis C virus infection.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

No vaccines or other drugs for the prevention of hepatitis C are known. Williams (WO 02/066022 A1; 2002 Aug 19; priority 2001 Feb; IDS 5/31/2005 reference BE)

points out that the known treatments for hepatitis C are not satisfactory, interferon alpha is the mainstay of therapy, with specific antivirals compounds, such as ribavirin and lamivudine; responses are rarely greater than 50% (p. 2, lines 18-22); hepatitis C vaccines have not proven effective (p. 3, line 1). These statements reflect the state of the art is unpredictable with respect to prevention of hepatitis C.

(5) The relative skill of those in the art:

The relative skill in the art is high

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for an inhibitory effect of ATRA on the RAR receptor; clinical trials to monitor the effect of ATRA on hepatitis C patients have been proposed.

However, the specification does not provide examples or reasoning in support of the prevention of hepatitis C by administration of ATRA.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the lack of effective vaccines, the failure of treating hepatitis C 50% of the time with normally used therapies, and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

12. Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 9, 15, 17-18, 28, 32-34, 52, 53, 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Herget et al. (US 7,341,717; priority date 2001 Apr).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Herget teaches administration of all-trans-retinoic acid to patients with chronic hepatitis C infection, in particular to patients who failed to respond to previous interferon or ribavirin therapy (col. 26, ll. 14-27); the oral dosage unit is a 10 mg capsule (col. 26, ll. 30); carriers, excipients and diluents (col. 17, ll. 24-26, 55-56). The activations recited in claims 53 and 55 would be inherent for treatment of hepatitis C with all-trans-retinoic acid.

15. Claims 9, 15-18, 28, 32-35, 52-53 and 55 are rejected under 35 U.S.C. 102(a) & (e) as being anticipated by Williams (WO 02/066022 A1; 2002 Aug 19; priority 2001 Feb; IDS 5/31/2005 reference BE).

Williams teaches a method of treating hepatitis, including hepatitis C, comprising administering all-trans retinoic acid (abstract; p. 8, lines 3-6; claim 8); administration to an individual (in vivo; pp. 8-9, Example 1); effective doses include 50-150 mg every other day (p. lines 20-21), oral dosing (p. 9, line 19); admixture with carriers and excipients (p. 12, line 7-8) ; unit dosages (p. 12, lines 16-17), tablets and capsules (p. 12, lines 18-19); topical application (p. 13, line 6); response rates to interferon alpha and ribavarin are rarely greater than 50% for hepatitis B or C (implying administration to an individual that is a non-responder to these therapies; p. lines 19-22). The activations recited in claims 53 and 55 would be inherent for treatment of hepatitis C with all-trans-retinoic acid.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (WO 02/066022 A1; 2002 Aug 19; priority 2001 Feb).

Claim 9 is rejected as outline above under 35 USC 102(a) & (e). With respect to claims 10-11, Williams does not teach the composition % by weight recited in the instant claims. It would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the formulations for i.v., topical, and oral administration, which

would have led to the fractions of the active compound within the ranges of the instant compound. The motivation would have been the routine optimization of dosing and formulations.

Double Patenting

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 9, 15, 18, 32-33, 52-53, 55 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-4 of U.S. Patent No. 7,341,717 in view of Yu, et al. ("Plasma Selenium Levels and Risk of Hepatocellular Carcinoma among Men with Chronic Hepatitis Virus Infection"; 1999; American Journal of Epidemiology; 150(4): 367-374).

The differences between the claims of the patent and the instant claims is 1) the patent claims recite a combination therapy of selenium or a selenium salt and a second

agent, which includes all-trans-retinoic acid, which is not required by the instant claims; 2) the patent claims are drawn to a method for inhibiting or downregulating hepatitis C viral replication, whereas the instant claims are drawn to a method for regulating the production of hepatitis C virus in an individual and/or for preventing and/or treating hepatitis C; however, the patient population would be the same; 3) the patent claims do not contain information about oral application, including tablets and capsules, whereas the instant claims require these details. Yu teaches that there is a risk associated with low selenium levels and hepatocellular carcinoma among men with chronic hepitits B or C (abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine selenium with all-trans-retinoic acid for the treatment of individuals with hepatitis C. The motivation would have been a desire to reduce the risk of developing cancer in individuals with Hepatitis B. The administration of the combination therapy would have inherently resulted in both methods of the patent and instant claims. it would also have been obvious to administer 10 mg oral dosages of all-trans-retinoic acid, since both applications teach that dosage (of Vesanoid capsule) in the proposed clinical study.

22. Claims 9, 15, 18, 32-33, 52-53, 55 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 6, 10-12, 15 of copending Application No. 10/075295 in view of Yu, et al. ("Plasma Selenium Levels and Risk of Hepatocellular Carcinoma among Men with Chronic Hepatitis Virus Infection"; 1999; American Journal of Epidemiology; 150(4): 367-374).

The differences between the claims of the copending and the instant claims is 1) the copending claims recite a combination therapy that includes selenium with all-trans-retinoic acid for example, which is not required by the instant claims, but is one embodiment; and 2) the patent claims do not contain information about oral application, including tablets and capsules, whereas the instant claims require these details. Yu teaches that there is a risk associated with low selenium levels and hepatocellular carcinoma among men with chronic hepitits B or C (abstract). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine selenium with all-trans-retinoic acid for the treatment of individuals with hepatitis C. The motivation would have been a desire to reduce the risk of developing cancer in individuals with Hepatitis B. The administration of the combination therapy would have inherently resulted in both methods of the copending and instant claims. it would also have been obvious to administer 10 mg oral dosages of all-trans-retinoic acid, since both applications teach that dosage (of Vesanoid capsule) in the proposed clinical study.

This is a provisional obviousness-type double patenting rejection.

23. Two examples of double patenting have been identified. Since applicants are most familiar with their own applications, applicants must bring to the attention any other applications that may have potential double patenting claims.

Conclusion

24. No claim is allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614